

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSENDER FOR PATENTS PO Box 1430 Alexandria, Virginia 22313-1450 www.unplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/585,378	04/06/2007	Bernhard Sixt	3787	5954	
278 MICHAEL L S	278 7590 12/30/2009 MICHAEL J. STRIKER			EXAMINER	
103 EAST NECK ROAD			KOAGEL, JONATHAN BRYAN		
HUNTINGTON, NY 11743			ART UNIT	PAPER NUMBER	
			3744		
			NOTIFICATION DATE	DELIVERY MODE	
			12/30/2009	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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striker@strikerlaw.com

Application No. Applicant(s) 10/585,378 SIXT ET AL. Office Action Summary Examiner Art Unit JONATHAN KOAGEL 3744 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 20 July 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 30-32.34.35.38 and 44-51 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 30-32,34,35,38 and 44-51 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Claim Objections

Claim 31 is objected to because of the following informalities: The recitation "further comprising an additional chilling jacket" (claim 31 line 2) should be changed to -further comprising a chilling jacket-- for clarity and proper antecedent basis, since no
other chilling jacket has been claimed in claim 30, from which claim 31 depends. Also
the recitation "an insulating jacket which shields said additional chilling jacket" (claim 31
lines 4-5) should be changed to --an insulating jacket which shields said chilling jacket-for proper antecedent basis and clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30, 32, 46 and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coetzee US Patent No. 6,467,299 B1 and Ryu US Patent No. 6,068,882 and further in view of Owen US Patent No. 6,209,343 B1 and Drake US Patent No. 3,858,410.

Regarding claim 30, Coetzee teaches in figs. 1 and 2, a transport container for keeping frozen material chilled, comprising an insulating chamber (chamber that container 16 fits into), an insulation 12 that encloses said insulating chamber, an inner

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container 16 removably arranged in said insulating chamber said inner container 16 having at least one chilling chamber 13 for the material and at least one refrigerant chamber (chamber between 16 and 18) which is permanently hermetically sealed (according to fig. 2, chamber between 16 and 18 is fully enclosed), and a refrigerant 14 located in said refrigerant chamber and giving off cold by solid/liquid phase transformation (Coetzee discloses using many types of refrigerants in solid, liquid and gel form, column 3 lines 13-56). Coetzee does not teach a superinsulation, no insulation between said inner container and said chilling chamber or a pure organic substance for the refrigerant.

Ryu teaches a superinsulation with a coefficient of thermal conductivity of 0.005 W/m K that is used in cryogenic (low temperature) applications (column 1 line 51-column 2 line 16).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Coetzee with the teachings of Ryu to include a superinsulation in order to provide a cost effective and easy to handle insulation for cryogenic applications as well as an insulation having superior performance characteristics (Ryu column 1 lines 50-53 and column 2 lines 58-60). Coetzee as modified by Ryu fails to explicitly teach no insulation between said inner container and said chilling chamber or a pure organic substance for the refrigerant.

Owen teaches in fig. 1, an inner container 10 removably arranged in an insulating chamber 20a, 20b, the inner container 10 having a chilling chamber 5 such that there is no insulation between said inner container 10 and said chilling chamber 5.

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It would have been obvious to a person of ordinary skill in the art at the time of invention to modify the combined teachings of Coetzee and Ryu with the teachings of Owen to include no insulation between said inner container and said chilling chamber in order to increase the amount of heat transfer that occurs between the sample being cooled and the refrigerant. The increase in heat transfer rate will allow the material to stay frozen for a longer period of time, preserving the material until needed. Coetzee as modified by Ryu and Owen fails to explicitly teach a refrigerant that is a pure organic substance.

Drake teaches a reusable heat sink means in a cooler undergoing a phase change such as mercury (column 2 lines 8-23, mercury is known in the art to be a pure organic substance and having a phase change at a temperature of -39 degrees Celsius which is in the range of -15 to -100 degrees Celsius). Regarding the heat of melting of at least 50 J/ml, it is inherently taught by Drake that at a temperature range of -15 to -100 degrees Celsius, mercury has a heat of melting of 50 J/ml.

It would have been obvious to one of ordinary skill in the art at the time of invention to further modify Coetzee, Ryu and Owen with the teachings of Drake to include a refrigerant with a phase change temperature of -39 degree Celsius in order to use the transport container with a variety of applications that require cooling of a material at temperatures below ambient temperature.

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Regarding claim 32, Coetzee as modified above teaches the invention as disclosed and Coetzee further teaches in fig. 2, wherein said refrigerant chamber 14 is configured like said chilling chamber 13 in said inner container 16.

Regarding claim 46, Coetzee as modified above teaches the invention as disclosed and Coetzee further teaches in fig. 2, said insulation 12 is configured as a cup with said insulating chamber (chamber that container 16 fits into) which is adapted to said inner container 16 and is closable by an insulating closure 28 (column 3 lines 44-46).

Regarding claim 48, Coetzee as modified above teaches the invention as disclosed but fails to explicitly teach said refrigerant is a refrigerant which melts/solidifies as the temperature is less than or equal to -30 degrees Celsius.

However, it would have been obvious to a person of ordinary skill in the art at the time of invention select a refrigerant which melts/solidifies as the temperature is less than or equal to -30 degrees Celsius, since it has been held to be within the general skill of a worker in the art to select known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. The use of a refrigerant that melts/solidifies at this temperature will allow the material to be kept frozen for a longer period of time, resulting in further preservation of the material.

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Regarding claim 49, Coetzee as modified above teaches the invention as disclosed but fails to explicitly teach said refrigerant is a refrigerant which melts/solidifies as the temperature is less than or equal to -85 degrees Celsius.

However, it would have been obvious to a person of ordinary skill in the art at the time of invention select a refrigerant which melts/solidifies as the temperature is less than or equal to -85 degrees Celsius, since it has been held to be within the general skill of a worker in the art to select known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. The use of a refrigerant that melts/solidifies at this temperature will allow the material to be kept frozen for a longer period of time, resulting in further preservation of the material.

Regarding claim 50, Coetzee as modified above teaches the invention as disclosed but fails to explicitly teach the refrigerant is selected from the group as claimed. However, it would have been obvious to a person of ordinary skill in the art at the time of invention select a refrigerant from the group as claimed, since it has been held to be within the general skill of a worker in the art to select known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 51, Coetzee as modified above teaches the invention as disclosed and Ryu further teaches a superinsulation with a coefficient of thermal conductivity of 0.005 W/m K that is used in cryogenic (low temperature) applications

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(column 1 line 51-column 2 line 16). Coetzee as modified fails to explicitly teach a superinsulation has a coefficient of thermal conductivity of less than or equal to 0.002 W/m K. However, the specific thermal conductivity of 0.002 is recognized as a result effective variable, i.e. a variable which achieves a recognized result. In this case a thermal conductivity of less than or equal to 0.002 would provide a higher insulation for the frozen material being transported. This insulation would allow the frozen material to stay frozen for a longer period of time, resulting in further preservation of the frozen material.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coetzee, Ryu, Owen and Drake as applied to claim 30 above and further in view of Guice US Patent No. 5.355.684.

Regarding claim 31, Coetzee as modified discloses the invention as claimed above and Ryu further teaches a superinsulation with a coefficient of thermal conductivity of less than 0.01 W/m K but fails to explicitly teach a chilling jacket with a jacket chamber with a second refrigerant, and an insulating jacket of a superinsulation.

However, Guice teaches in fig. 2, a chilling jacket 34 having a jacket chamber (chamber defined by 34) which contains a refrigerant 28 with a solid/liquid phase transition in a temperature range from 0 to -15 degrees Celsius, and an insulating jacket 38 which shields said chilling jacket 34 from outside, and contains insulation (column 6 lines 49-65 and column 9 line 58-column 10 lines 16). Guice discloses in column 8 a mixture of ethylene glycol and water which can be varied depending on how long the

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shipment needs to stay cold. Therefore, the mixture can be adjusted to perform a phase transformation at a range of 0 to -15 degrees Celsius.

It would have been obvious to one of ordinary skill in the art at the time of invention to further modify Coetzee, Ryu, Owen and Drake with the teachings of Guice to include a chilling jacket with a jacket chamber and an insulating jacket surrounding it in order to protect the cryogenically insulated vessel from mechanical damage as well as providing extra thermal insulation in order to preserve the sample for the allotted amount of storage time (Guice column 10 line 66-column 11 line 2).

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coetzee, Ryu, Owen and Drake as applied to claim 30 above and further in view of Cook et al. US Patent No. 5.934.099.

Regarding claim 34, Coetzee as modified discloses the invention as claimed above and Coetzee further teaches in fig. 2, the inner container is composed of a low temperature resistant plastic high density polyethylene (column 3 lines 19-34). It is well known in the art that this material has a high resistance to low temperatures and is used in applications for housing and protecting vials of biomedical samples.

Cook teaches in figs. 1 and 2, a refrigerant container 14 with a refrigerant chamber 62 for arrangement in said insulating chamber 28.

It would have been obvious to one of ordinary skill in the art at the time of invention to further modify Coetzee, Ryu, Owen and Drake with the teachings of Cook to include an additional refrigerant chamber in order to increase the rate of heat transfer.

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from the sample container to the refrigerant containers in order to keep the temperature sensitive sample cooled for the allotted period of storage time.

Regarding claim 35, Coetzee as modified above teaches the invention as disclosed but fails to explicitly teach the refrigerant chamber has a filling opening, and wherein said filling opening is welded closed.

However Cook teaches in fig. 2, a refrigerant chamber 62 has a filling opening 44 wherein the filling opening is welded closed (column 6 lines 15-64).

It would have been obvious to one of ordinary skill in the art at the time of invention to further modify Coetzee, Ryu, Owen and Drake with the teachings of Cook to include the refrigerant chamber has a filling opening and wherein the opening is welded closed in order to provide a means for filling the chamber with refrigerant. The use of welding will ensure that the refrigerant does not leak out and contaminate the frozen material or the surrounding environment.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coetzee, Ryu, Owen and Drake as applied to claim 30 above and further in view of Connelly US Patent No. 52,269.

Regarding claim 38, Coetzee as modified discloses the invention as claimed above but fails to explicitly teach the refrigerant chamber has a filling opening closed by a screw stopper and welded closed on an outside.

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However, Connelly teaches in fig. 2, a filling opening on a bottle is closed on an inside by a screw stopper (column 1 paragraph 2). Regarding the welding of the stopper on the outside after it is inserted into the filling opening, the general concept of welding and such permanent attachment methods are well known in the art. The welding of the stopper would prevent the stopper from accidentally becoming unscrewed and the possibility of the refrigerant contaminating the sample in the container.

It would have been obvious to one of ordinary skill in the art at the time of invention to further modify Coetzee, Ryu, Owen and Drake with the teachings of Connelly to include a stopper and welding, that when combined with Coetzee, the refrigerant chamber would have a filling opening which is closed on an inside by a screw stopper and welded closed on an outside in order to seal the container in which liquids or other materials are kept in order to exclude the air within the container (Connelly paragraph 2).

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coetzee, Ryu, Owen and Drake as applied to claim 30 above and further in view of Yomei JP Publication No. 09243223 A.

Regarding claim 44, Coetzee as modified above teaches the invention as disclosed but fails to explicitly teach said inner container has a double walled hollow cylinder including an inner wall and an outer wall and also a bottom at one end and an annular wall at the other end, said refrigerant chamber being formed between said inner

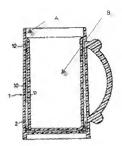
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wall and said outer wall, and said annular wall and said bottom, and said chilling chamber being arranged centrally and delimited by said inner wall and said bottom.

However, Yomei teaches in fig. 1, an inner container 1 has a double walled hollow cylinder 12 including an inner wall 11 and an outer wall 10, and also a bottom at one end and an annular wall A (See annotated figure below) at the other end, a refrigerant chamber being formed between said inner wall 11 and said outer wall 10 and said annular wall A and said bottom, a chilling chamber B (See annotated figure below) being arranged centrally and delimited by said inner wall 11 and said bottom.

It would have been obvious to a person of ordinary skill in the art at the time of invention to modify the combined teachings of Coetzee, Ryu, Owen and Drake with the teachings of Yomei to include a double walled hollow cylinder including an inner wall and an outer wall and also a bottom at one end and an annular wall at the other end, said refrigerant chamber being formed between said inner wall and said outer wall, and said annular wall and said bottom, and said chilling chamber being arranged centrally and delimited by said inner wall and said bottom in order to increase the rate of heat transfer that occurs between the material in the chilling chamber and the refrigerant within the refrigerant chamber. By having the frozen material in that close of proximity to the refrigerant, the frozen material will be able to stay frozen for a longer period of time, resulting in further preservation of the frozen material.

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Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coetzee, Ryu, Owen, Drake and Yomei as applied to claim 44 above and further in view of Mosby US Patent No. 6,032,481.

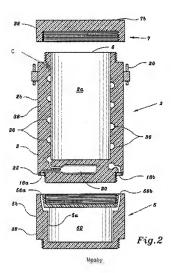
Regarding claim 45, Coetzee as modified above teaches the invention as disclosed but fails to explicitly teach said inner wall of said cylinder has a thread for an element which closes said chilling chamber and is selected from the group consisting of a screw cover and a screw stopper.

However Mosby teaches in fig. 2, an inner wall C (See annotated figure below) of a cylinder 3 has a thread for an element 7 which closes a chilling chamber 2a and is selected from the group consisting of a screw cover.

It would have been obvious to a person of ordinary skill in the art at the time of invention to modify the combined teachings of Coetzee, Ryu, Owen, Drake and Yomei

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with the teachings of Mosby to include a thread for an element which closes said chilling chamber in order to prevent heat transfer between the frozen material and the surrounding ambient air. The screw cover will prevent the frozen material from thawing, which will increase the amount of time that the frozen material can be preserved.



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Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coetzee, Ryu, Owen and Drake as applied to claim 30 above and further in view of Mullens et al. US Patent No. 6,119,465.

Regarding claim 47, Coetzee as modified above teaches the invention as disclosed but fails to explicitly teach where said insulation is surrounded by a rigid protective tube having ends which are closed by a cover.

However, Mullens teaches in fig. 1, a transport container with insulation 20 surrounded by a rigid protective tube 22 having ends which are closed respectively by a cover D (See annotated figure below).

It would have been obvious to a person of ordinary skill in the art at the time of invention to modify the combined teachings of Coetzee, Ryu, Owens and Drake with the teachings of Mullens to include a rigid protective tube surrounding the insulation in order to provide a protective surface for the insulation so the insulation does not become damaged during transport of the frozen material. If the insulation becomes damaged, it does not insulate as well, so the protective tube will insure that the frozen material stays frozen during transport.

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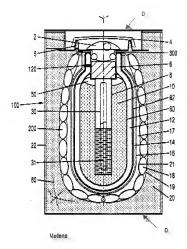


Fig. 1

Response to Arguments

Applicant's arguments filed 7/20/09 have been fully considered but they are not persuasive.

In response to applicant's arguments regarding the Coetzee reference and the transport container not freezing the material, the examiner respectfully disagrees with the applicants interpretation of the claim. First, the preamble limitation states that the transport container has the intended use of keeping frozen material chilled. The recitation that "for keeping frozen material chilled" has been given limited patentable

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weight because it has been held that a preamble is denied the effect of limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Roble*, 88 USPQ 478 (CCPA 1951). Secondly, the preamble limitation does not require that the transport container keep the material frozen. All that is required is that there is frozen material placed in the container, and the container keeps the material chilled. This will result in the material being frozen and stored in the transport container.

In regards to the Coetzee reference and the inner container not being removably arranged, the examiner disagrees. With the proper tooling and force, the inner container can be removable from the insulating chamber. The claim does not state that the container has to be continuously removable from the chamber, rather where the inner container is removably arranged in the chamber. Coetzee discloses in figure 2 that the inner container 16 is removably arranged, as the inner container is not perminately fixed in the chamber, as apparent in the figure. Therefore, the inner container is interpreted to be removably arranged within the insulating chamber.

With respect to the applicant's argument regarding the refrigerant chamber not being hermetically sealed, the examiner respectfully disagrees. As shown in figure 1 of Coetzee, the refrigerant chamber (chamber between 16 and 18) is clearly shown as being hermetically sealed because the two elements 16 and 18 are shown as being fully sealed and the chamber inbetween being fully enclosed, therefore it can be considered as being hermetically sealed. The two elements 16 and 18 are sealed together in figure

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1 at the rim of each element, so that the refrigerant will be contained within the refrigerant chamber. In order to insert a sample into the transport container, the lid is removed and the sample placed inside. When this happens, the two elemets 16 and 18 are not moved, rather the cap is removed so that access to the chilling chamber can occur. Because the two elements 16 and 18 are not disturbed in this process, the refrigerant chamber is interpreted as being hermetically sealed.

Regarding the argument of the mercury refrigerant as disclosed by Drake not being an organic substance and not being able to go through a phase change, the examiner disagrees. The refrigerant, mercury as disclosed by Drake is an organic substance and the liquid mercury can go through a phase change as mercury as a refrigerant is well known in the art to do so. The applicant specifically discloses on page 3 of the specification that solidified mercury has a melting point of about -39 degrees Celsius, thereby stating that mercury has a phase changing property. Therefore, the mercury refrigerant as disclosed by Drake in the rejection of claim 30 still stands.

In response to applicant's argument that there is no suggestion to combine the references, in particular for claim 30, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references in claim 30 came from the knowledge

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available to one of ordinary skill in the art, and therefore the cited prior art did not need to suggest the modifications that were made to Coetzee.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN KOAGEL whose telephone number is (571)270-7396. The examiner can normally be reached on Monday through Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cheryl Tyler can be reached on (571)272-4834 or Frantz Jules (571)272Application/Control Number: 10/585,378 Page 19

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6681. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. K./ Examiner, Art Unit 3744 18 December 2009 /Cheryl J. Tyler/ Supervisory Patent Examiner, Art Unit 3744